510(k) Summary of Safety and Effectiveness

Proprietary Name:	AxSOS™ Locking Plate System
Common Name:	Bone plates and screws
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories - 21 CFR §888.3030; Smooth or threaded metallic bone fixation fastener - 21 CFR §888.3040
Regulatory Class:	Class II
Product Codes:	87 HRS: Plate, Fixation, Bone; 87 HWC: Screw, Fixation, Bone
For Information contact:	Kelly Kucharczyk, Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6455 Fax: (201) 831-3461
Date Prepared:	September 23, 2011

Description:

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to add the pediatric indication to a specific subset of plates, screws and inserts of the previously cleared Stryker Plating System (K060514). The components from the previously cleared system, some of which carry the pediatric indication, will make-up the system to be marketed as the AxSOS™ Locking Plate System. The indications for use will clarify which components will include the pediatric indication.

Intended Use:

The Stryker AxSOS™ Small Fragment Plating System is intended for internal fixation, stabilization and support of fractures as well as bone fixation after osteotomies in the following:

In Adults:

- 4mm Waisted Compression Plate – radius, ulna, distal tibia, fibula, distal humerus, clavicle
- 4mm Locking Insert
- 4mm Locking Screws
- 3.5mm Cortical Screws
- 3mm One Third Tubular Plate – fibula, metatarsals, metacarpals
- 4mm Reconstruction Plate – humerus, pelvis

In Pediatrics:

- 4mm Waisted Compression Plate – radius, ulna, distal tibia, distal humerus, clavicle
- 4mm Locking Insert
- 4mm Locking Screws
- 3.5mm Cortical Screws

The Stryker AxSOS™ Basic Fragment Plating System is intended for internal fixation, stabilization and support of long bone fractures as well as bone fixation osteotomies in the following:

In Adults:

- 5mm Waisted Compression Plate – Broad –femur, tibia, humerus, pelvis
- 5mm Waisted Compression Plate – Narrow – femur, tibia, humerus, pelvis
- 5mm Locking Insert
- 5mm Locking Screws
- 4.5mm Cortical Screws
- 5mm Reconstruction Plate – femur, tibia, humerus, pelvis

In Pediatrics:

- 5mm Waisted Compression Plate – Broad –femur, tibia, humerus
- 5mm Waisted Compression Plate – Narrow – femur, tibia, humerus
- 5mm Locking Insert
- 5mm Locking Screws
- 4.5mm Cortical Screws

Indications:
The Stryker AxSOS™ Small Fragment Plating System is intended for internal fixation, stabilization and support of fractures as well as bone fixation after osteotomies in the following:

In Adults:
- 4mm Waisted Compression Plate – radius, ulna, distal tibia, fibula, distal humerus, clavicle
- 4mm Locking Insert
- 4mm Locking Screws
- 3.5mm Cortical Screws
- 3mm One Third Tubular Plate – fibula, metatarsals, metacarpals
- 4mm Reconstruction Plate – humerus, pelvis

In Pediatrics:
- 4mm Waisted Compression Plate – radius, ulna, distal tibia, distal humerus, clavicle
- 4mm Locking Insert
- 4mm Locking Screws
- 3.5mm Cortical Screws

The Stryker AxSOS™ Basic Fragment Plating System is intended for internal fixation, stabilization and support of long bone fractures as well as bone fixation osteotomies in the following:

In Adults:
- 5mm Waisted Compression Plate – Broad –femur, tibia, humerus, pelvis
- 5mm Waisted Compression Plate – Narrow – femur, tibia, humerus, pelvis
- 5mm Locking Insert
- 5mm Locking Screws
- 4.5mm Cortical Screws
- 5mm Reconstruction Plate – femur, tibia, humerus, pelvis

In Pediatrics:
- 5mm Waisted Compression Plate – Broad –femur, tibia, humerus
- 5mm Waisted Compression Plate – Narrow – femur, tibia, humerus
- 5mm Locking Insert
- 5mm Locking Screws
- 4.5mm Cortical Screws

Summary of Technologies:
Device comparisons showed that the proposed device is substantially equivalent in intended use, design, materials and performance characteristics to the following predicate devices:

K082807- Synthes 3.5 and 4.5mm Locking Compression Plate (LCP) System
K060514- Stryker Locked Plating System

Non-Clinical Testing:
Non-clinical laboratory testing was performed for the subject plates, screws and inserts to determine substantial equivalence. As there are no additional design, process, material or performance characteristic changes, no general tests for verification and validation are necessary. However, an additional comparative compression fatigue testing was conducted for the subject plates, screws and insert to evaluate the fatigue resistance in long-term pediatric use. The testing demonstrated that the AxSOS™ Locking Plate Systems are substantially equivalent to devices currently cleared for market with pediatric indications.

Clinical Testing:
Clinical testing was not required for this submission.

Conclusion:
The AxSOS™ Locking Plate System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Corporation
% Ms. Kelly Kucharczyk
325 Corporate Drive
Mahwah, New Jersey 07430

DEC 19 2011

Re: K112926
Trade/Device Name: AxSOS™ Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 29, 2011
Received: October 3, 2011

Dear Ms. Kucharczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___K112926_____

Device Name: AxSOS™ Locking Plate System

The Stryker AxSOS™ Small Fragment Plating System is intended for internal fixation, stabilization and support of fractures as well as bone fixation after osteotomies in the following:

In Adults:
- 4mm Waisted Compression Plate – radius, ulna, distal tibia, fibula, distal humerus, clavicle
- 4mm Locking Insert
- 4mm Locking Screws
- 3.5mm Cortical Screws
- 3mm One Third Tubular Plate – fibula, metatarsals, metacarpals
- 4mm Reconstruction Plate – humerus, pelvis

In Pediàtrics:
- 4mm Waisted Compression Plate – radius, ulna, distal tibia, distal humerus, clavicle
- 4mm Locking Insert
- 4mm Locking Screws
- 3.5mm Cortical Screws

The Stryker AxSOS™ Basic Fragment Plating System is intended for internal fixation, stabilization and support of long bone fractures as well as bone fixation osteotomies in the following:

In Adults:
- 5mm Waisted Compression Plate – Broad –femur, tibia, humerus, pelvis
- 5mm Waisted Compression Plate – Narrow – femur, tibia, humerus, pelvis
- 5mm Locking Insert
- 5mm Locking Screws
- 4.5mm Cortical Screws
- 5mm Reconstruction Plate – femur, tibia, humerus, pelvis

In Pediatrics:
- 5mm Waisted Compression Plate – Broad –femur, tibia, humerus
- 5mm Waisted Compression Plate – Narrow – femur, tibia, humerus
- 5mm Locking Insert
- 5mm Locking Screws
- 4.5mm Cortical Screws

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112926